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10/579,674	05/18/2006	Olivier Dutrecq	DECLE67.002APC	4873
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2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			BHAT, NARAYAN KAMESHWAR	
			ART UNIT	PAPER NUMBER
,			1634	
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			NOTIFICATION DATE	DELIVERY MODE
			11/07/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com eOAPilot@kmob.com

	LA U Al N.	A No code			
	Application No.	Applicant(s)			
	10/579,674	DUTRECQ ET AL.			
Office Action Summary	Examiner	Art Unit			
	Narayan K. Bhat	1634			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the	correspondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATIO 36(a). In no event, however, may a reply be ti vill apply and will expire SIX (6) MONTHS fron cause the application to become ABANDONI	N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 09 Oc	<u>ctober 2007</u> .				
2a) ☐ This action is FINAL . 2b) ☑ This	This action is FINAL . 2b)⊠ This action is non-final.				
	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.			
Disposition of Claims					
4) ⊠ Claim(s) 1-17 is/are pending in the application. 4a) Of the above claim(s) 9-17 is/are withdrawn 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) 1-8 is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or	from consideration.				
Application Papers					
9) The specification is objected to by the Examine	•				
10)⊠ The drawing(s) filed on <u>18 May 2006</u> is/are: a)[
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Ex					
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
•					
Attachment(s)	·				
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summar Paper No(s)/Mail D				
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5/18/2006 & 5/8/2007.	5) Notice of Informal 6) Other:				

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DETAILED ACTION

Election/Restrictions

- 1. Claims 1-17 are pending in this application.
- 2. Applicant's election of group I, claims 1-8, in the reply filed on October 9, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
- 3. Claims 9-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 9, 2007.
- 4. Claims 1-8 are under prosecution.

35 USC § 112 Sixth Paragraph

5. The following is a quotation of the sixth paragraph of 35 U.S.C. 112:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

6. The limitation of "abrasive sampling means" in claims 1 and 4 (line 4) is <u>not</u> being treated under 35 USC 112, sixth paragraph as it does not meet 3-prong test, because claim does not recite the phrase "means for" and the "abrasive means" further modifies the structure by reciting "abrasive means capable of retaining biological materialin the form of cells". Therefore claims 1 and 4 are not examined under 112 sixth paragraph

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analysis.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 8. Claims 1-2 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Volossiouk et al (Applied and Environmental Microbiology, 1995, 61, 3972-3976, herein after Volossiouk).

Regarding claim 1, Volossiouk teaches a method of assaying nucleic acids by PCR, that is molecular hybridization, that include taking samples of biological material from farm soils and grinding using a mortar and pestle and further teaches soil provided the abrasion and grinding is entirely sufficient to disruption of tissues and cells (Fig. 1, pgs. 3972 and 3973, column 2, paragraphs 4 and 2), thus teaching abrasive sampling means to collect biological materials in the form of cells.

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Volossiouk also teaches isolating nucleic acids from the cells (Fig. 1, pg. 3973, column 2, paragraph 3) and assaying the nucleic acids by PCR, which requires molecular hybridization with primer and sample (Fig. 2, pg. 3973, column 1 and 2, paragraph 2 and 3).

Regarding claim 2, Volossiouk teaches a method of collecting farm soils and sand, clay and fine gravels from six diverse regions in Canada (pg. 3972, column 2, paragraph 4) and grinding using mortar and pestle surrounded by air, thus teaching the sampling of biological material is done in the surrounding air.

Regarding claim 6, Volossiouk teaches a method wherein the assaying by molecular hybridization is done by polymerase chain reaction (PCR) (Fig. 1, last step, pg. 3973 column 1, paragraphs 2 and 3).

Regarding claim 7, Volossiouk teaches a method that includes determining the presence of a verticillium wilt pathogenic agent in the biological material by PCR, i.e., a molecular hybridization (pg. 3972 column 2, paragraph 2).

Regarding claim 8, Volossiouk teaches a method of detecting a plant wilt pathogen wherein the biological material consists of material of plant origin (pgs. 3972 and 3973, column 2, paragraph 2).

9. Claims 1-4 and 6 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Fenrich et al (USPGPUB NO. US 2004/01219537 published Nov. 4, 2004 herein after Fenrich).

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Regarding claim 1, Fenrich teaches a method of assaying nucleic acids by PCR, which requires molecular hybridization with primer and sample and further teaches taking samples of biological material by a sampling device (Fig. 1, # 10) comprising abrasive sampling means (paragraph 0050-0052) capable of retaining biological material in the form of cells (paragraph 0050-0052).

Fenrich also teaches isolating nucleic acids from the cells (paragraphs 0087-0089) and further teaches assaying the nucleic acids by molecular hybridization (paragraph 0090).

Regarding claim 2, Fenrich teaches a method of sampling of epidermal biological material from humans and animals especially from skin surface which is surrounded by air (paragraphs 0014-0017 and 0049-0050).

Regarding claim 3, Fenrich teaches a method for collecting biological samples wherein the sampling is done outside of a laboratory where the assaying will be done (See Fig. 25 for a kit to collect the sample, paragraph 0085), and further comprising transporting the abrasive sampling means loaded with their respective samples of biological material to said laboratory (paragraph 0084).

Regarding claim 4, Fenrich teaches a method that includes an extraction of the nucleic acids, comprising the steps of washing the cells from abrasive surface followed by collecting the DNA, thus teaching immersing the abrasive sampling means loaded with their respective samples of biological material into an extraction buffer (paragraph 0056).

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Fenrich also teaches agitating the extraction buffer, separating the nucleic acids, and recovering clarified solution containing the nucleic acids (paragraph 0089).

Regarding claim 6, Fenrich teaches a method wherein the assaying by molecular hybridization is done by polymerase chain reaction (paragraph 0090).

Claim Rejections - 35 USC § 103

- 10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 12. Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volossiouk et al (Applied and Environmental Microbiology, 1995, 61, 3972-3976, herein after Volossiouk) and in view of Fenrich et al (USPGPUB NO. US 2004/01219537 published Nov. 4, 2004 herein after Fenrich).

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The claim 5 is dependent on claim 4, which is dependent on claim 1. The claim 3 is dependent on claim 1. Teachings of Volossiouk regarding claim 1 is described previously in this office action.

Regarding claim 3, Volossiouk teaches collecting samples from farm soils and sand, clay and fine gravels from six diverse regions in Canada (pg. 3972, column 2, paragraph 4) and further teaches soil itself provided the abrasion means (Fig. 1, pgs. 3972 and 3973, column 2, paragraphs 4 and 2) but silent about transporting the abrasive sampling means loaded with their respective samples of biological material to the laboratory. However transporting samples from the site of collection to the laboratory was known in the art at the time the claimed invention was made as taught by Fenrich, who teaches a method for collecting biological samples wherein the sampling is done outside of a laboratory where the assaying will be done (See Fig. 25 for a kit to collect the sample, paragraph 0085), and further teaches transporting the abrasive sampling means loaded with their respective samples of biological material to the laboratory (paragraph 0084). Fenrich also teaches transporting samples in sterile bag with vapor barrier to reduce microbial contamination (paragraph 0084).

It would have been prima facia obvious to one having the ordinary skill in the art at the time the invention was made to substitute transporting samples under sterile conditions of Fenrich in the sample collection method of Volossiouk with a reasonable expectation of success.

An artisan would have been motivated to substitute transporting samples under sterile conditions of Fenrich in the sample collection method of Volossiouk with the

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expected benefit of reducing microbial contamination of the sample as taught by Fenrich (paragraph 0084).

Regarding claim 4, Volossiouk teaches a method that include extraction of the nucleic acids, comprising the steps of mixing the abrasive sampling means loaded with their respective samples of biological material into an extraction buffer (Fig. 1, step 5) and agitating the extraction buffer, separating the nucleic acids, and recovering clarified solution containing the nucleic acids (Fig. 1, steps 6-8, pg. 3973, column 1, paragraph 1).

Regarding claim 5, Volossiouk teaches a method of nucleic acid extraction wherein the separation step consists of a centrifugation, and the supernatant constitutes the clarified solution (pg. 3973, column 1, paragraph 1).

Volossiouk does not teach explicitly immersing the abrasive sampling means loaded with their respective sample of biological material in to an extraction buffer. However immersing the abrasive sampling means loaded with their respective sample of biological material in to an extraction buffer was known in the art at the time the claimed invention was made as taught by Fenrich, who teaches a method that includes an extraction of the nucleic acids, comprising the steps of washing the cells from abrasive surface followed by collecting the DNA, thus teaching immersing the abrasive sampling means loaded with their respective samples of biological material into an extraction buffer (paragraph 0056).

It would have been prima facia obvious to one having the ordinary skill in the art at the time the invention was made to substitute immersion of cells removed from

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abrasive means of Fenrich in the nucleic acid isolation method of Volossiouk with a reasonable expectation of success.

An artisan would have been motivated to substitute immersion of cells removed from abrasive means of Fenrich in the nucleic acid isolation method of Volossiouk with the expected benefit of efficiently removing precious biological samples from abrasive means as taught by Fenrich thus providing more cells in the nucleic acid isolation method of Volossiouk to collect higher amounts of nucleic acids.

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Narayan K. Bhat, Ph. D.

Examiner

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